

REMARKS

Finality of the Office Action

In response to the Final Office Action, Applicants respectfully request that the Examiner enter the foregoing amendments and consider the following remarks because the claims have been placed in condition for allowance. In the alternative, Applicants request that the claim amendments be entered because they better place the claims in condition for an appeal. For example, the amendments to independent claims 1, 15, and 39 remove the rejection of those claims under 35 U.S.C. 102(e) as being allegedly anticipated by *Burshteyn*. See page 12 *infra*.

Cancellation of Claims

Claims 4, 32, and 46 are canceled without prejudice, waiver, or disclaimer. Applicants take this action merely to reduce the number of disputed issues and to facilitate early allowance and issuance of other claims in the present application. Applicants reserve the right to pursue the subject matter of the canceled claims in a continuing application, if Applicants so choose, and do not intend to dedicate any of the canceled subject matter to the public.

Drawings

The drawings were objected to under 37 CFR 1.83(a) because it allegedly “fail to show the washer (140) as described in the specification.” *Office Action* at 1. As directed by the Office, the proposed drawing that was omitted in the response dated March 21, 2005, is now submitted herewith. FIG. 1 has been amended to indicate a washer 140. The amendment has been made in red ink to clearly depict the proposed drawing correction. If the Office finds the proposed drawing correction acceptable, Applicants will submit a new formal FIG. 1 upon receipt of a Notice of Allowance.

Claims Rejections under 35 U.S.C. § 102

Claims 1, 6, 7, 13, 15-16, 18-22, and 39-45 have been rejected under 35 U.S.C 102(e) as allegedly being anticipated by U.S. Patent No. 6,692,702 to Burshteyn *et al* (“*Burshteyn*”). Applicants respectfully traverse.

First, the Office Action contends that the provisional patent application (“the ‘248 provisional”), to which the current application claims priority, does not provide support for many of the current claim features and specifically recites “there is no support for a filter material chosen from polypropylene, cellulose nitrate, nylon, polyvinylidene fluoride or HPVM membrane.” *Final Office Action* at 7. Further, the Office Action states that there is no support in the ‘248 provisional for a flow cytometer image acquisition system. Therefore, the Office Action provided that the effective filing date is the actual filing date of the instant application - June 24, 2003. Applicants respectfully traverse each of these assertions. According to the Manual of Patent Examination Procedure (MPEP) § 706.02(V) (D), “[i]f the application properly claims benefit under ... to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35 U.S.C. 112 by the provisional application.”

Applicants maintain that support for the claims can be found at least at pages 3-5 and 10-11 of the ‘248 provisional. Specifically, the ‘248 provisional provides support for the claims in at least the following passages: “In brief the device consists of a centrifuge tube or similar vessel in which are placed one or more filters with discrete molecular weight cutoffs. In the simplest form, the filter is composed of an inert material with uniform pores, or holes, of known sizes.” (page 3, 5th para., lines 3-5); “the filter material... can be produced with a spectrum of different pore sizes....” (page 3, 5th para., lines 11-12); “the binary readout of the DFS columns will simplify development of automated readers to determine assay results.” (page 4, 2nd para., line 4); “After centrifugation, aggregates are retained above the filter while single cells have passed through the filter into the bottom of the tube. This allows a simple binary readout of “1” or “0” for whether cells are retained above the filter or not.” (page 5, 5th para., lines 2-4); and “The binary readout...should also greatly facilitate automated data acquisition and interpretation since an automated optical reader would only have to distinguish between the presence or absence of cells above the filter(s).” (page 5, 4th para., lines 7-9).

Therefore, the effective filing date of the instant application is the filing date of the ‘248 provisional, which precedes the filing date of *Burshteyn*. Applicants respectfully request that the rejection be withdrawn.

Nevertheless, to advance prosecution and facilitate early allowance of the claims, Applicants submit the following arguments with respect to *Burshteyn*.

(a) Claim 1

Independent claim 1 recites “wherein the image acquisition system is designed to detect the presence of interactions between components in the assay sample and the reagent, **wherein said interactions are evidenced by agglutination**.” (Emphasis added). This feature is not taught or suggested by *Burshteyn*. Instead of employing an image acquisition system designed to detect interactions evidenced by agglutination as recited in claim 1, *Burshteyn* discloses “analyzing the test sample from which the interferants have been removed using flow cytometry...” and “running the processed test sample mixture on a flow cytometer equipped to quantitatively measure the amount **of fluorescently-labeled antigen-specific antibody** associated with each cell in the processed test sample mixture.” *Burshteyn* at col.16, lines 41-52 (emphasis added). The flow cytometer of *Burshteyn* is designed to measure antibodies after interferants have been removed; the flow cytometer is not designed to measure agglutinations, as recited in claim 1. Thus, *Burshteyn* does not disclose the image acquisition system of claim 1.

In addition, and as a separate ground for allowability of claim 1, amended claim 1 recites “wherein the image acquisition system in close proximity to the sample separation system.” This is a feature of canceled dependent claim 4 that has not been rejected based on *Burshteyn*. Therefore, *Burshteyn* does not anticipate claim 1. In addition, it would not have been obvious to one of ordinary skill in the art to place the image acquisition in close proximity to the sample preparation system based on the teachings of *Burshteyn*. As noted above, *Burshteyn* employs a flow cytometer designed for different purposes than the image acquisition system of claim 1. There is no apparent need in *Burshteyn* to have its flow cytometer in close proximity to the rest of *Burshteyn*’s disclosed apparatus. In the instant claims, however, because the image acquisition system is designed to detect interactions among components in the assay sample and reagent, timing may be significant and it is desirable to have the image acquisition system in close proximity to the sample preparation system.

For at least this reason, all of the features of independent claim 1 are not taught or suggested by *Burshteyn*. Applicants therefore respectfully request that the rejection be withdrawn.

(b) Claim 15

Independent claim 15 recites “wherein the cytometer is designed to detect the presence of interactions between components in the assay sample and the reagent, ***wherein the interactions are evidenced by agglutination.***” This feature is not taught or suggested by *Burshteyn*. As noted above, the flow cytometer of *Burshteyn* is designed to measure antibodies after interferants have been removed; the flow cytometer is not designed to measure agglutination, as recited in claim 15. Thus, *Burshteyn* does not disclose the image acquisition system of claim 15.

In addition, and as a separate ground for allowability of claim 15, amended claim 15 recites “an incubator in which the vessel can be placed, wherein the incubator houses the vessel while the assay sample and the reagents react.” This is a feature of dependent claim 2 that has not been rejected based on *Burshteyn*. Therefore, *Burshteyn* does not anticipate claim 15. In addition, it would not have been obvious to one of ordinary skill in the art to include an incubator in an immunological assay system based on the teachings of *Burshteyn*. *Burshteyn* discloses a filtration device, not a system that houses an assay sample and reagent while they react, and then detects those interactions, as recited in independent claim 15. There is no apparent need or motivation in *Burshteyn* to include an incubator.

For at least this reason, all of the features of independent claim 15 are not taught or suggested by *Burshteyn*. Applicants therefore respectfully request that the rejection be withdrawn.

(c) Claim 39

Independent claim 39 recites “***determining the presence of agglutination*** with the flow cytometry.” (Emphasis added). This step is not taught or suggested by *Burshteyn*. Instead of determining the presence of agglutination as recited in claim 39, *Burshteyn* discloses “running the processed test sample mixture on a flow cytometer equipped to quantitatively ***measure the amount of fluorescently-labeled antigen-specific antibody*** associated with each cell in the

processed test sample mixture.” *Burshteyn* at col.16, lines 41-52 (emphasis added). *Burshteyn* discloses measuring antibodies after interferants have been removed; it does not teach or suggest measuring agglutinations, as recited in claim 39. Thus, *Burshteyn* does not anticipate the method of claim 39.

In addition, and as a separate ground for allowability of claim 39, amended claim 39 recites the step of “spreading the sample mixture over a bottom surface of a reaction vessel through ***low speed centrifugation in order to facilitate interactions between reaction components.***” This is a feature of canceled dependent claim 46 that has not been rejected based on *Burshteyn*. Therefore, *Burshteyn* does not anticipate claim 39. In addition, it would not have been obvious to one of ordinary skill, based on the teachings of *Burshteyn*, to “spread[]the sample mixture over a bottom surface of a reaction vessel” utilizing the unique properties of the selected filter materials. As noted above, *Burshteyn* discloses “method ***utilizing a filter to remove interferants*** from a body fluid prior to analysis”, which is a more usual use of filter material. *Burshteyn* at col. 6, lines 44-45. There is no apparent need in *Burshteyn* to have its flow cytometer in close proximity to the rest of *Burshteyn*’s disclosed apparatus. In the instant claims, however, because the image acquisition system is designed to detect interactions among components in the assay sample and reagent, timing may be significant and it is desirable to have the image acquisition system in close proximity to the sample preparation system.

For at least this reason, all of the features of independent claim 1 are not taught or suggested by *Burshteyn*. Applicants therefore respectfully request that the rejection be withdrawn.

(d) Claims 7, 13, 16, 18-22, and 40-45

Because independent claims 1, 15, and 39 are allowable over *Burshteyn*, then for at least this reason, their dependent claims 7, 13, 16, 18-22, and 40-45 are also allowable. Applicants therefore respectfully request that the rejection of these claims be withdrawn as well. There may be other reasons why the dependent claims are allowable over *Burshteyn*.

Claim Rejections under 35 U.S.C. § 103

Claims 1-5, 8, 10-12, 15, 17-31, and 35-46 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko *et al.* (“*Yaremko*”) in view of U.S. Patent No. 5,308,990 to Takahashi *et al.* (“*Takahashi*”). Claims 32-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over *Yaremko* and *Takahashi* and further in view of U.S. Patent No. 6,008,040 to Datar. Applicants respectfully traverse the rejections. In addition, claims 4 and 46 have been canceled without prejudice, waiver, or disclaimer, thus rendering the rejection of these claims moot.

Claims 1, 15, 23, and 39 are independent claims. As noted above, each of these independent claims has been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over the combination of *Yaremko* in view of additional (secondary or tertiary) cited art. There is at least one fundamental distinction between the claimed embodiments of the present independent claims and *Yaremko*, which makes the rejections of the independent claims inapplicable. Specifically, the independent claims all recite “a filter material chosen from at least one of the following: [a, claim 1] polypropylene; [a, claim 1] cellulose nitrate; [a, claim 1] nylon; polyvinylidene fluoride; and HPVM membrane.”

In contrast to the independent claims, *Yaremko* does not disclose nor suggest such a filter. Instead, at column 6, lines 21-26, *Yaremko* teaches a different type of filter material. There, *Yaremko* states:

A multitude of very small, transparent glass beads, having diameters on the order of magnitude of 10 to 100 micrometers, are deposited in and form a filter in the lower portion of each microcolumn. Alternately, the lower portion of each microcolumn may be provided with a suitable gel that functions in the same general way as the microbeads.

Yaremko teaches beads or porous gel, because this type of filter is required to perform depth filtration, and thus separate cells through a thick filter. *Yaremko* uses a long-column containing gel or beads as a filter substance, with separation occurring *within* the column. ***The method of Yaremko would be unworkable using the filter materials recited in the present claims*** Furthermore, the claimed method would not work using the bed/gel column technology disclosed by *Yaremko*. The claimed systems utilize thin filters in order to take advantage of

their surface properties and effects in order to “spread[] the sample mixture” **on top of** the filter. For at least this reason, independent claims 1, 15, 23, and 39 patently define over the cited art.

Takahashi fails to remedy this deficiency. In fact, the Office Action admits that “[n]either Yaremko et al. nor Takahashi et al. teach the particular filter materials recited in claim 32-33.” *Office Action* at 6. It should be noted that dependent claim 32 (canceled and incorporated into independent claim 23) recites “wherein the filter comprises a material selected from a polypropylene, a nylon, a cellulose nitrate and polyvinylidene fluoride.” Instead, the Office Action relies on the teachings *Datar* as supplying this teaching. Applicants respectfully disagree in part. Although *Datar* may disclose the use of polyester, nylon, cellulose acetate, and PVDF, it does not teach or suggest the use of polycarbonate track-etched membrane.

In addition, *Datar* does not appear to be analogous to the present claims. *Datar* teaches how to separate different cell populations from one another using a “cascade flow” of fluid. This is not related at all to the invention in instant application. The present claims do not recite separating different cells into distinct populations. Furthermore, *Datar* teaches depth filtration, where a thick filter medium (in their case made of multiple filter layers) is used for separation. In this way, separation occurs **within** the filter in *Datar*. In the present independent claims, a membrane filter is recited with a pore size that retains cellular components or agglutinated components **on top of the filter**. Thus, not all of the teachings of the independent claims are taught or suggested by *Yaremko* and *Takahashi* in combination with *Datar*. Even combining the cited references would not lead one skilled in the art to abandon the depth filtration of *Yaremko* and *Datar* for the surface filtration recited in the independent claims. In light of this explicitly-claimed feature, the applied combination of *Datar* with *Yaremko* is inappropriate.

In addition, each of the independent claims have been amended to recite the feature of “the filter material including a plurality of pores with a pore size from about 0.1 microns to about 3 microns” in claims 1, 23, and 39 and “the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns” in claim 15. The cited references do not teach or suggest the features of these pore sizes.

It is well settled law that in order to properly support an obviousness rejection under 35 U.S.C. § 103, there must have been some teaching *in the prior art* to suggest to one skilled in the

art that the claimed invention would have been obvious. *W. L. Gore & Associates, Inc. v. Garlock Thomas, Inc.*, 721 F.2d 1540, 1551 (Fed. Cir. 1983). More significantly,

“The consistent criteria for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this [invention] should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. ...” Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure... In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill in the art is charged with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention.”

In re Dow Chemical Company, 837 F.2d 469, 473 (Fed. Cir. 1988) (Emphasis added).

In this regard, Applicants note that there must not only be a suggestion to combine the functional or operational aspects of the combined references, but that the Federal Circuit also requires the prior art to suggest *both* the combination of elements *and* the structure resulting from the combination. *Stiftung v. Renishaw PLC*, 945 Fed.2d 1173 (Fed. Cir. 1991). Therefore, in order to sustain an obviousness rejection based upon a combination of any two or more prior art references, the prior art must properly suggest the desirability of combining the particular elements to create the immunological assay system with *all* of the features as claimed by the Applicants.

When an obviousness determination is based on multiple prior art references, there must be a showing of some “teaching, suggestion, or reason” to combine the references. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579, 42 USPQ2d 1378, 1383 (Fed. Cir. 1997) (also noting that the “absence of such a suggestion to combine is dispositive in an obviousness determination”).

Evidence of a suggestion, teaching, or motivation to combine prior art references may flow, *inter alia*, from the references themselves, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. See *In re Dembiczak*, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be “clear and particular.” *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617.

If there is motivation or suggestion to combine selective teachings from multiple prior art references, one of ordinary skill in the art would not have viewed the present invention as

obvious. See *In re Dance*, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998); *Gambro Lundia AB*, 110 F.3d at 1579, 42 USPQ2d at 1383 (“The absence of such a suggestion to combine is dispositive in an obviousness determination.”).

Significantly, where there is not apparent disadvantage present in a particular prior art reference, then generally there can be no motivation to combine the teaching of another reference with the particular prior art reference. *Winner Int’l. Royalty Corp. v. Wang*, No 98-1553 (Fed. Cir. January 27, 2000).

Simply stated, the application of the combination of *Yaremko* with *Takahashi* and *Datar* against the independent claims of the present application is inappropriate, and for at least the forgoing reasons. Applicants respectfully submit that the rejections should be withdrawn for at least these reasons. Having set forth the forgoing, the undersigned will, below, address each independent claim.

(a) Independent Claim 1

The Office Action has rejected claim 1 as allegedly unpatentable over the combination of *Yaremko* in view of *Takahashi*. For at least the reasons that follow, Applicants respectfully disagree and request that the rejection be withdrawn.

Applicants respectfully submit that independent claim 1 defines over the combination of *Yaremko* and *Takahashi* for at least the reason that the combination fails to teach all of the features of claim 1. Specifically, as noted above, the cited references (including *Datar*) fail to teach or suggest the feature of “wherein the filter vessel comprises a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, the filter material including a plurality of pores with a pore size from about 0.1 microns to about 3 microns.”

In addition, *Yaremko* fails to teach or suggest the recited feature of claim 1 of “flow cytometer being designed to detect the presence of interactions between reagent antibodies and the assay sample cells.” Indeed, the Office Action admits this by stating, “*Yaremko et al.* differ from the instant invention in that the reference fails to teach a flow cytometer....” Office Action at 5. *Takahashi* fails to cure this deficiency. The portion of *Takahashi* relied on by the Office,

namely col. 1, lines 37-53, discloses the following:

On the other hand, as an immunological measurement method using particles, there is known a method, by which ***antigen concentration is measured by making latex spheres, with the surface of which an antibody is bound*** react with an antigen and ***measuring the agglutinated state of the latex spheres*** produced by the antigen-antibody reaction by the absorbance or the intensity of scattered light. Further, in order to analyze this agglutinated state with a high precision, there is known also a method, by which each agglutinated lump is led to a flow cytometer to be analyzed there. By this method it is possible to calculate the magnitude of each agglutinated lump, based on the intensity of scattered light to measure the antigen concentration with a high precision...

(Emphasis added). Thus, the disclosure of *Takahashi* is limited to measuring the agglutinated state of latex spheres to which antibodies are bound. Essentially, *Takahashi* simply describes using a flow cytometer to count the latex beads. *Takahashi* does not teach or suggest detecting interactions of a patient assay sample and reagent antibodies that are not bound to latex spheres.

Not only is *Takahashi* limited to measuring agglutinated state of latex spheres (not antigen-red blood cell interactions, *e.g.*, as in the independent claims), but *Takahashi* does not require filter materials since their assays do not require separation of cells from fluid. The filter of the independent claims is of a pore size the filters cellular components from fluid.

In addition, Applicants respectfully submit that the combination of *Yaremko* with *Takahashi* is improper. *Yaremko* is directed to an automated blood analysis system, whereas *Takahashi* is directed to a method and instrument “for measuring microparticles capable of detecting microparticles having a very low fluorescence intensity existing in liquid...” Id. at col. 1, lines 8-11 (emphasis added). The field of immunological testing is very broad. One searching for a solution to any problems of *Yaremko* would not look for answer in *Takahashi* because *Takahashi* is directing to detecting microparticles having an inherent fluorescence. In addition, it does not teach filtration or the use of filters to prepare cells for this process. *Yaremko* does not teach or suggest detecting microparticles having an inherent fluorescence. Thus, these two references are directed to very different aspects of the broad field of immunological testing.

For at least these reasons, as well as the reasons recited above, Applicants

respectfully submit that the combination of *Yaremko* and *Takahashi* does not render claim 1 obvious, and request that the rejection of claim 1 be withdrawn.

(b) Independent Claim 15

The Office Action rejected claim 15 on the same identical bases as claim 1 (see Office Action, pages 4-5). The undersigned respectfully submits that such a rejection is inappropriate, as the two claims are not coextensive in scope. However, for purposes of this response, and in an effort to advance the prosecution of this application, the undersigned submits that claim 15 patently defines over the cited art for at least some of the same reasons discussed above in connection with claim 1. In this regard, claim 15 includes the features of “a filter material chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane”, which is not taught or suggested by the cited references.

In addition, claim 15 recites the feature of “the filter material including a plurality of pores with a pore size from about 3 microns to about 5 microns.” This feature is also not taught or suggested by the cited references.

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* and *Takahashi* does not render claim 15 obvious, and request that the rejection of claim 15 be withdrawn.

(c) Independent Claim 23

The Office Action rejected claim 23 on the same identical bases as claim 1 (see Office Action, pages 4-5). The undersigned respectfully submits that such a rejection is inappropriate, as the two claims are not coextensive in scope. Although there are distinctions between claims 23 and claim 1, the filter of claim 23 is chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, and the filter means includes a plurality of pores with a pore size from about 0.1 microns to about 3 microns, similar to a corresponding elements of claim 1. As noted above, these features are not taught or suggested by the recited references.

In addition, claim 23 recites “analyzing the components in the vessel to determine the presence of interactions between the sample and reagent components, wherein the interactions are evidenced by agglutination... via a flow cytometer or a capillary cytometer.” As noted above, *Yaremko* does not disclose a cytometer in its system. *Takahashi* discloses a flow cytometer that analyzes the agglutinated state of *latex spheres* to which antibodies are bound. Thus, using a flow cytometer to measure only naturally occurring cellular components, as claimed in claim 23, is not taught or suggested by the combination of cited references.

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* and *Takahashi* does not render claim 23 obvious, and request that the rejection of claim 23 be withdrawn.

(5) Independent Claim 39

The Office Action rejected claim 39 on the same identical bases as claim 1 (see Office Action, pages 4-5). The undersigned respectfully submits that such a rejection is inappropriate, as the two claims are not coextensive in scope. Although there are distinctions between claims 39 and claim 1, the filter of claim 39 is chosen from at least one of the following: polyester mesh, nylon mesh, polycarbonate track-etched membrane, cellulose acetate membrane, and polyvinylidene difluoride filter membrane, and the filter means includes a plurality of pores with a pore size from about 0.1 microns to about 3 microns, similar to a corresponding elements of claim 1. As noted above, these features are not taught or suggested by the recited references.

In addition, claim 39 recites “analyzing the sample mixture via flow cytometry.” As noted above, *Yaremko* does not disclose a cytometer in its system. *Takahashi* discloses a flow cytometer that analyzes the agglutinated state of *latex spheres* to which antibodies are bound. Thus, using a flow cytometer to measure only naturally occurring cellular components, as claimed in claim 39, is not taught or suggested by the combination of cited references.

For at least these reasons, as well as the reasons recited above, Applicants respectfully submit that the combination of *Yaremko* and *Takahashi* does not render claim 39 obvious, and request that the rejection of claim 39 be withdrawn.

Because independent claims 1, 15, 23, and 39 are allowable, then for at least this reason, their dependent claims 2-3, 5, 8, 10-12, 17-33, and 35-45 are also allowable. Applicants

therefore respectfully request that the rejection of these claims be withdrawn as well.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1-3, 5, 7-8, 10-13, 15-31, 33, and 35-45 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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